DATAHOW

Transforming Process Development with AI-Technologies and a Digital Development Framework

AI-enabled Digital Bioprocessing

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AI & Advanced Analytics the next Milestone towards Pharma 4.0

Current approaches creating bottlenecks

SMART DEVELOPMENT & MANUFACTURING

AUTOMATION & DIGITAL TWINS

FROM: DATA DISILLUSIONMENT

BASIC TOOLS

NO STANDARD APPROACH

NEED FOR MANY DATA SCIENTISTS

LOCALISED KNOWLEDGE

Major Barriers to Insight

TO: DIGITAL BIOPROCESSING PLATFORM

DEMOCRATIZED

AI

STANDARDIZED

COLLABORATIVE KNOWLEDGE CREATION & SHARING

DATAHOWLAB

Democratised Process Knowledge Creation

DATA CAPTURE & MANAGEMENT

DIGITIZATION & CONNECTED DEVICES

AI-Technologies democratizing Access to deep process knowledge and the creation of Digital Twins

Transfer Learning

AI-enabled transfer of historical process knowledge across projects and scales to ***reduce experimental effort and accelerate development***

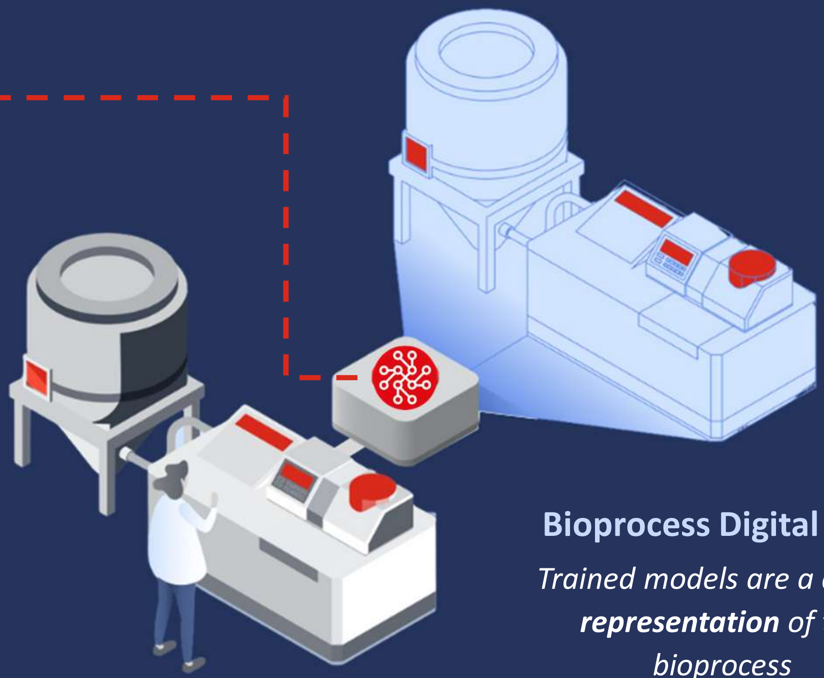
Hybrid Models (AI)

AI-enhanced models adapted to bioprocessing for ***accelerated learning & insight with less data***

Risk-Based Decision Support

(Bayesian Statistics)

Outcomes & analysis assessments based on ***probabilities***



Bioprocess Digital Twin

Trained models are a ***digital representation*** *of the bioprocess*

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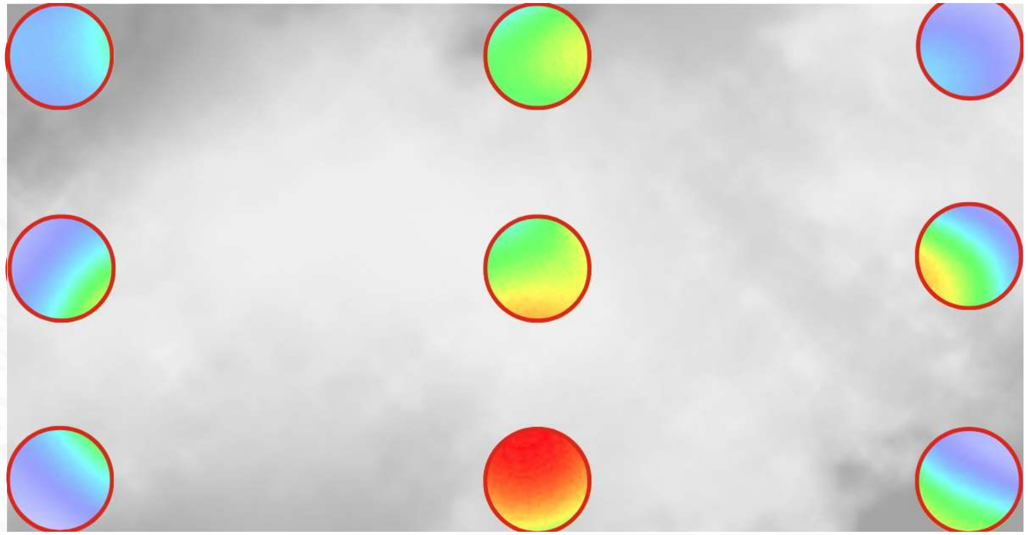
A Paradigm Shift for Experimental Planning & Design

Traditional Approach: DoE & Statistical Models

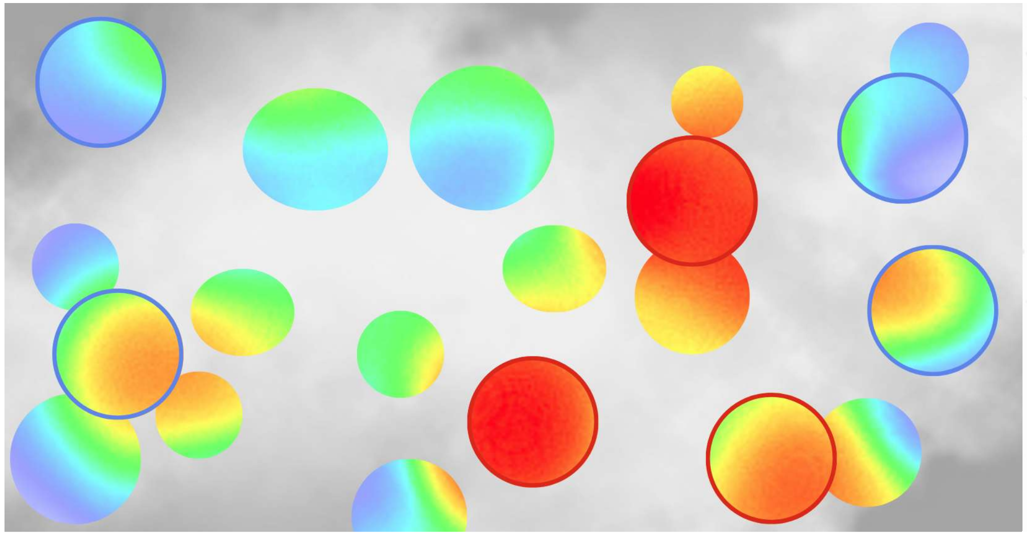


Fully dependent on new experimental data & analysis

Not leveraging existing bioprocessing knowledge

No learning from prior project data or insights

AI-driven Experimental Planning & Optimal Design



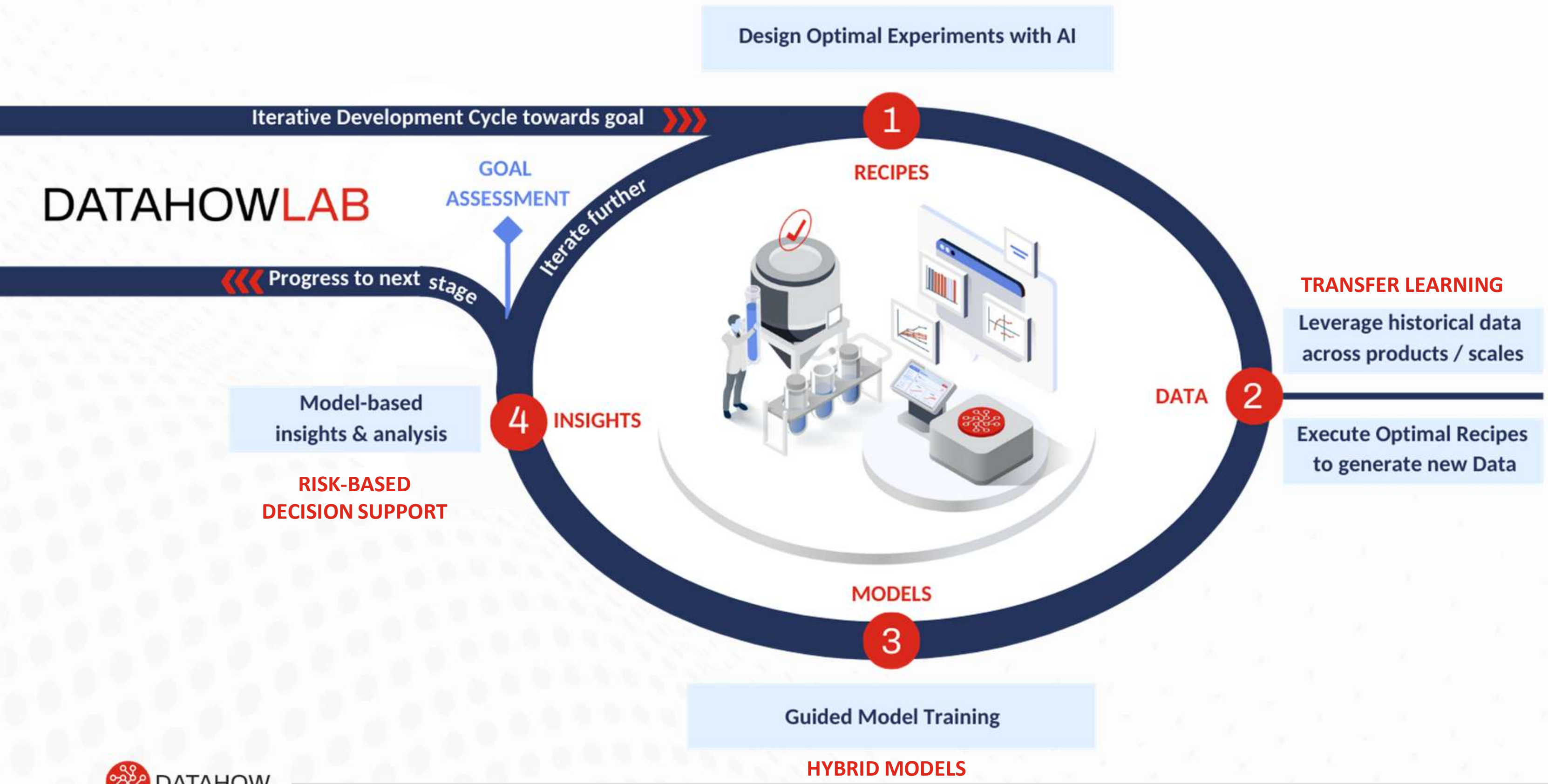
Fewer Targeted Experiments: **EXPLORE** gaps or **EXPLOIT** potential

Hybrid Models: Bioprocessing knowledge encoded mechanistically

Transfer Learning: transfer relevant historical project data & insights

Harnessed within a Digital Development Cycle

AI-Enabled Digital Bioprocessing Platform



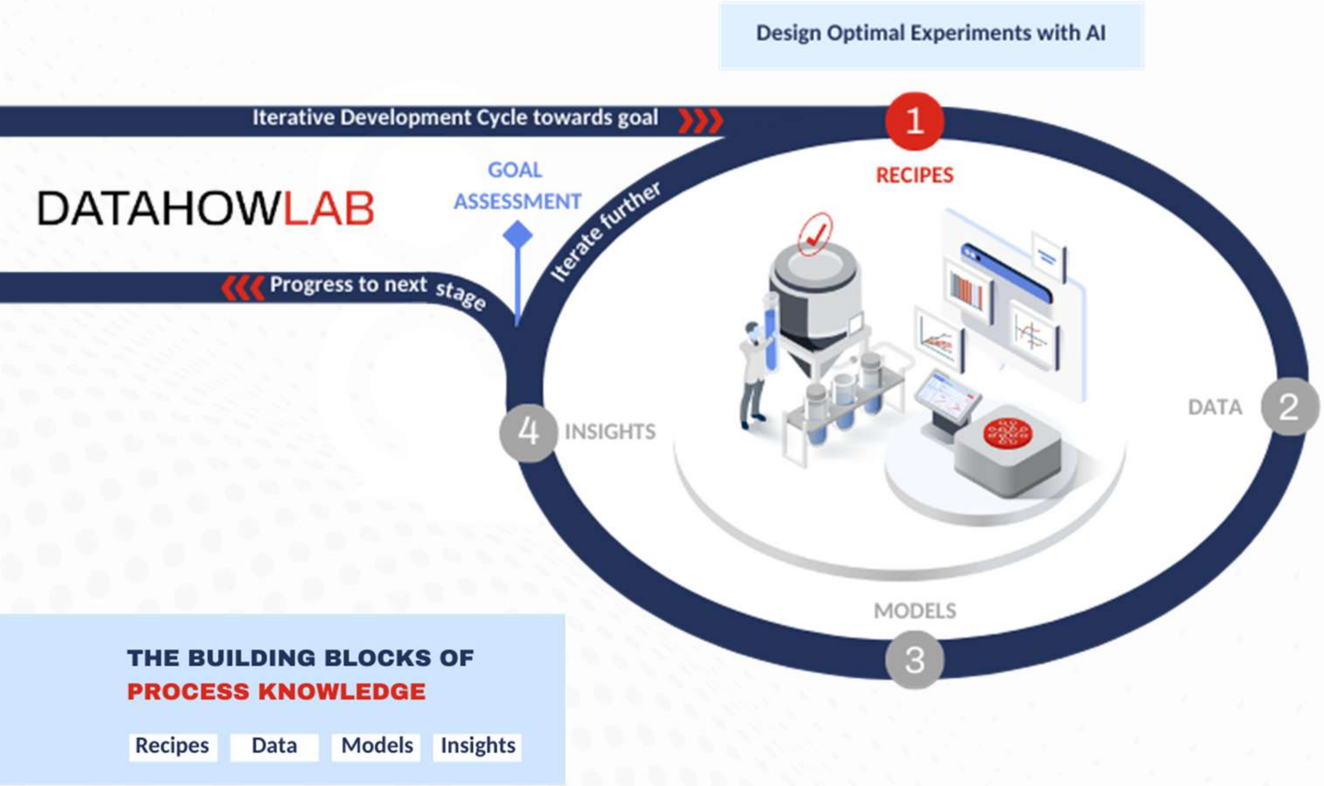
THAT SUPPORTS PROCESS STAKEHOLDERS

TO BUILD THE CORE ELEMENTS OF PROCESS KNOWLEDGE

- RECIPES
- DATA
- MODELS
- INSIGHTS

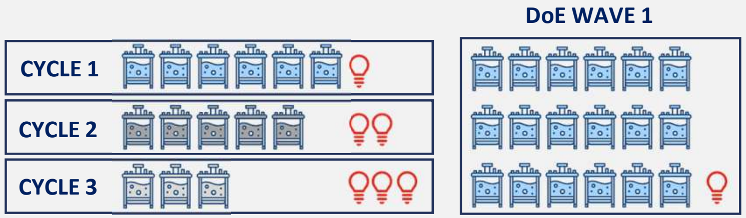
Design & Execute Shorter, High-Value, Experiment Cycles

Faster time, and lower cost to insight – iterate with supporting insight



1 RECIPES

- Experimental Designs which are optimized for the capabilities of Hybrid Models to **maximise insight with minimal, targeted, experimental data**
- Short, agile experimental cycles vs. extensive DoE waves to **reduce time and cost to insight and progress**

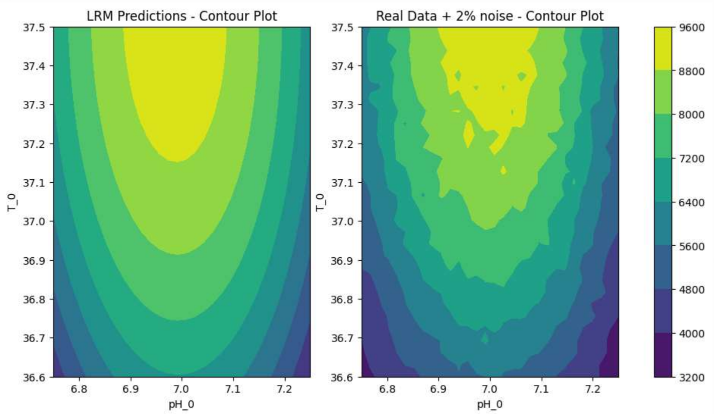


LHS + Hybrid Model vs Classical DOE

Much more with much less

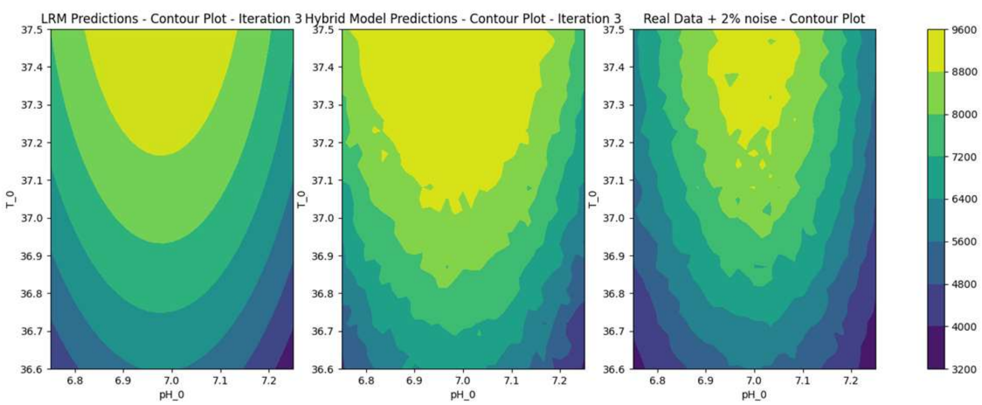
Target R^2: 90%

3 level FD – Reduced space – ca. 50 runs



Variable	pH_0	pH_after_switch	T_0	T_after_switch	Glc_feed	Gln_feed
Upper Bound	6.75	6.76	36.6	35.09	4.76	9.46
Lower Bound	7.25	7.46	37.5	35.59	5.66	9.96

Hybrid Model – Full Space – 20 runs

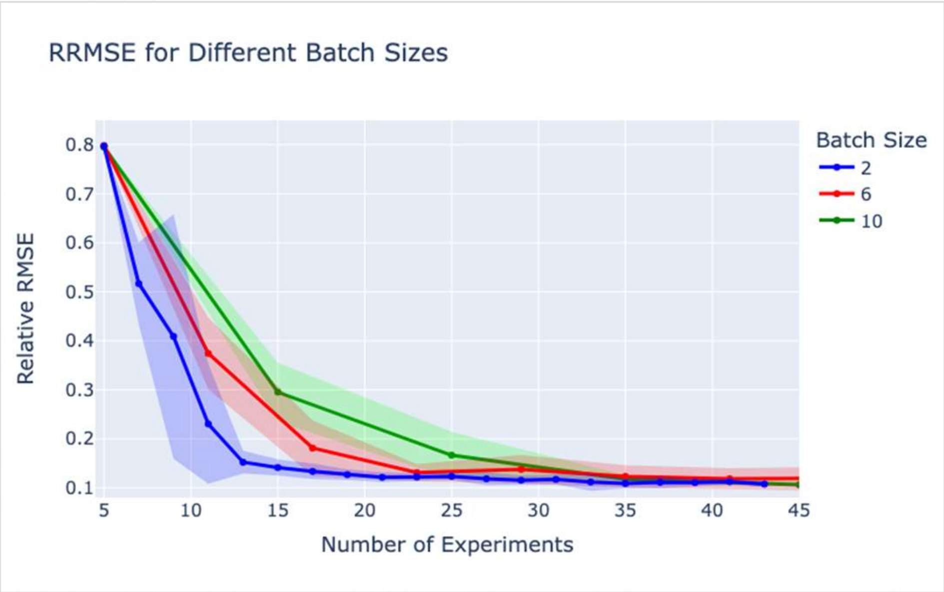


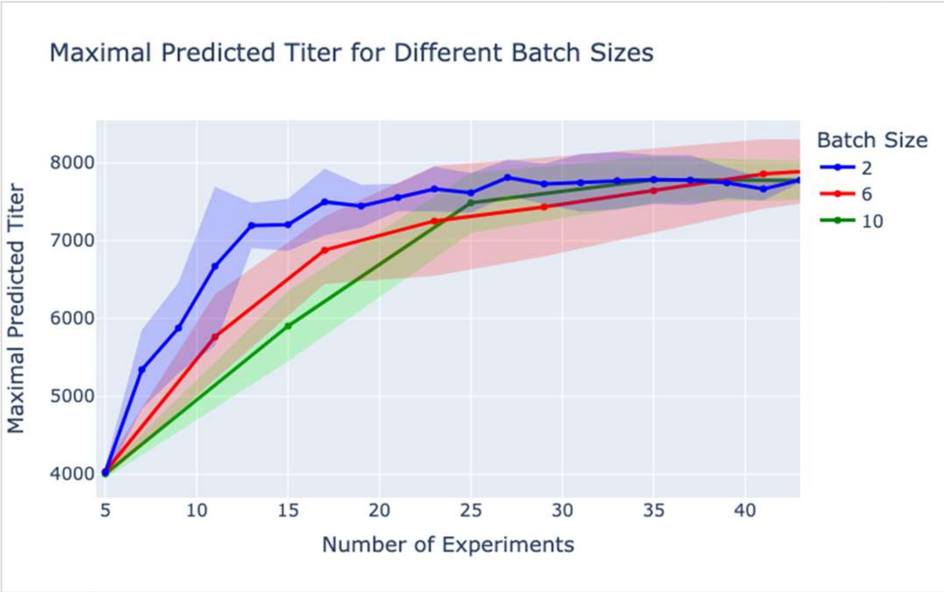
Variable	pH_0	pH_after_switch	T_0	T_after_switch	Glc_feed	Gln_feed
Upper Bound	6	6	36	35	2	6
Lower Bound	8	8	38	38	6	10

Validation Case: Hybrid Model for Cell Cultures

The Bayesian optimization methodology confirms the findings of the first study case

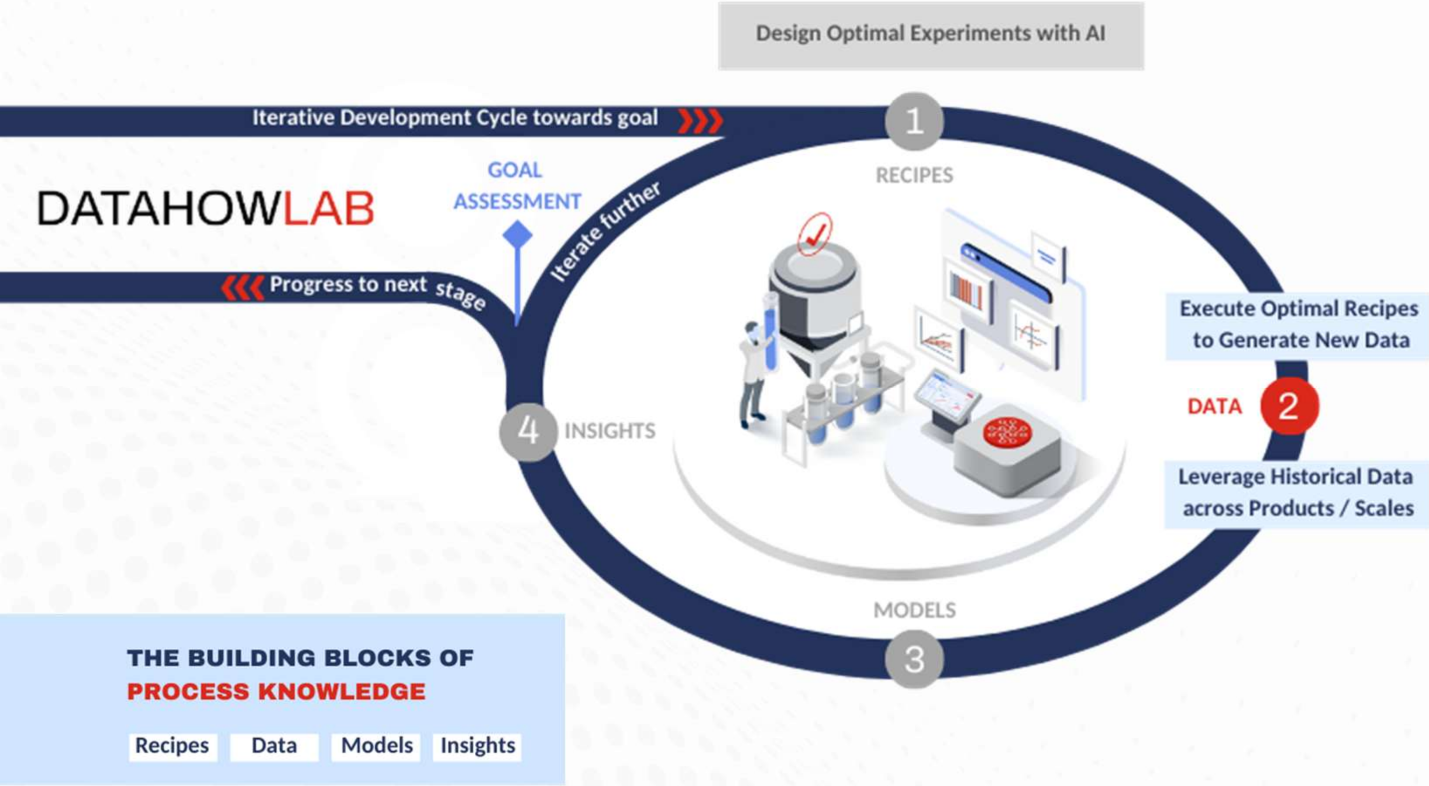
- Insilico Hybrid Model with 8 factors





Leverage Historical Data as a Development Asset

Reduce Experimental Effort and Drive Development Efficiency



2 DATA

- Generate new Experimental Data

- Compliment Experimental Data with Data from Relevant Historical Projects → **Transfer Learning**

TRANSFER LEARNING CASE STUDY REVIEW

Selected Case: Accelerate Clone Selection via Transfer Learning

Predicting molecule specific behaviour (Molecule - D) with only 3 runs

Historical Molecules

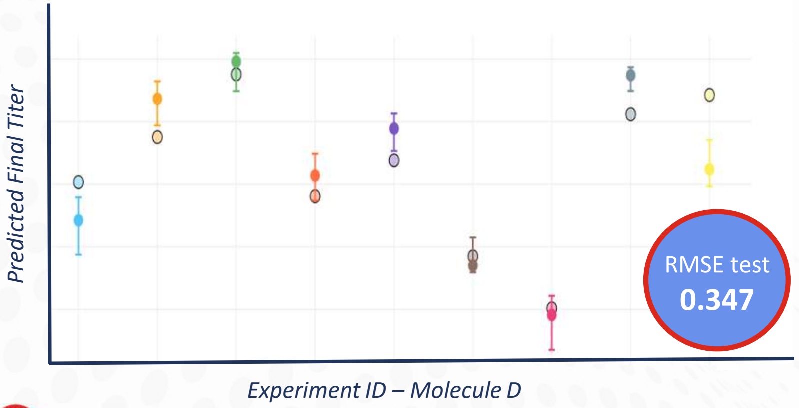
A – 15 runs

B – 15 runs

C – 15 runs

D - 3 runs | Predicted values

Predicted vs Test illustrates **high prediction accuracy**



Model trained on 15 runs of molecules A, B & C + 3 runs of D

- The behaviour of molecule D can be learned effectively from only 3 runs of D and transferred knowledge from molecules A-C.
- Transfer learning can significantly accelerate clone selection process
- The trained model could suggest optimal clone choice & process design

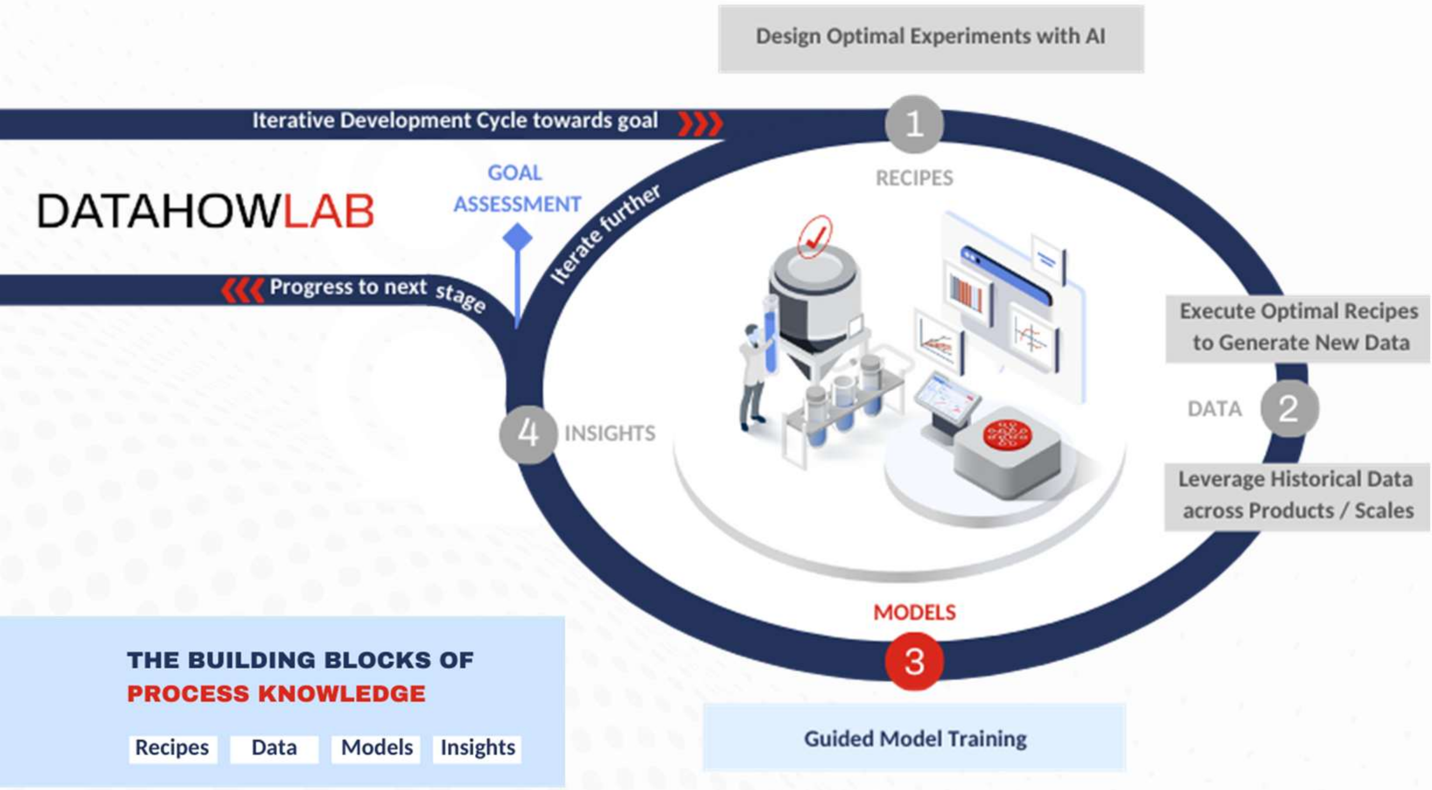
→ IMPACT: Reduction of Runs / Accelerated Development

Transfer learning can also be applied across scales

We have been able to learn and **predict large-scale titers** with no or only 1 mid-scale run before continuing to pilot scale.

Train AI-Powered Process Models with Confidence

Realise more Insight with Less Experimental Effort



3 HYBRID MODELS

- No-code, guided workflows, making model training and accessible to process scientists

1 2 3 4

- Use DataHow's transformative Hybrid Modeling technology to **maximize insight** and learning with **minimal experimental effort**

BMS CASE STUDY REVIEW

Mammalian USP

Optimization

Hybrid Models

Selected Case: Impact of Hybrid Models

Hybrid Models: Stronger CQA understanding with less data and experiments

Bristol Myers Squibb

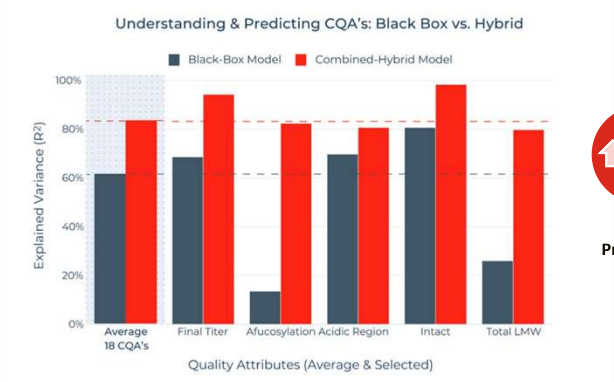
The Project:

Evaluate the ability of **DataHowLab's Hybrid Models** to accurately predict CQAs compared to industry state-of the-art "black box" models.

The Challenge:

48 (5-liter scale) experiments were designed and conducted by BMS to evaluate the impact of **12 process parameters** on **18 product CQAs.**

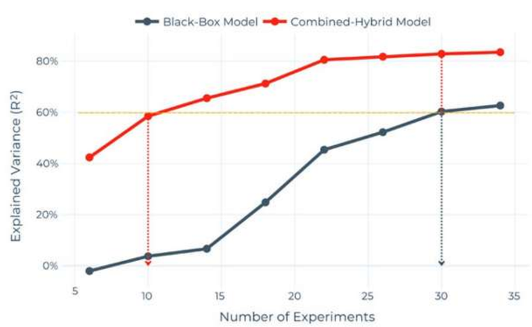
Understanding & Predicting CQAs: Black Box vs Hybrid



35%

CQA Prediction

# of Experiments required to predict CQAs: Black Box vs Hybrid



3x

Fewer experiments

Stronger CQA Prediction & Control

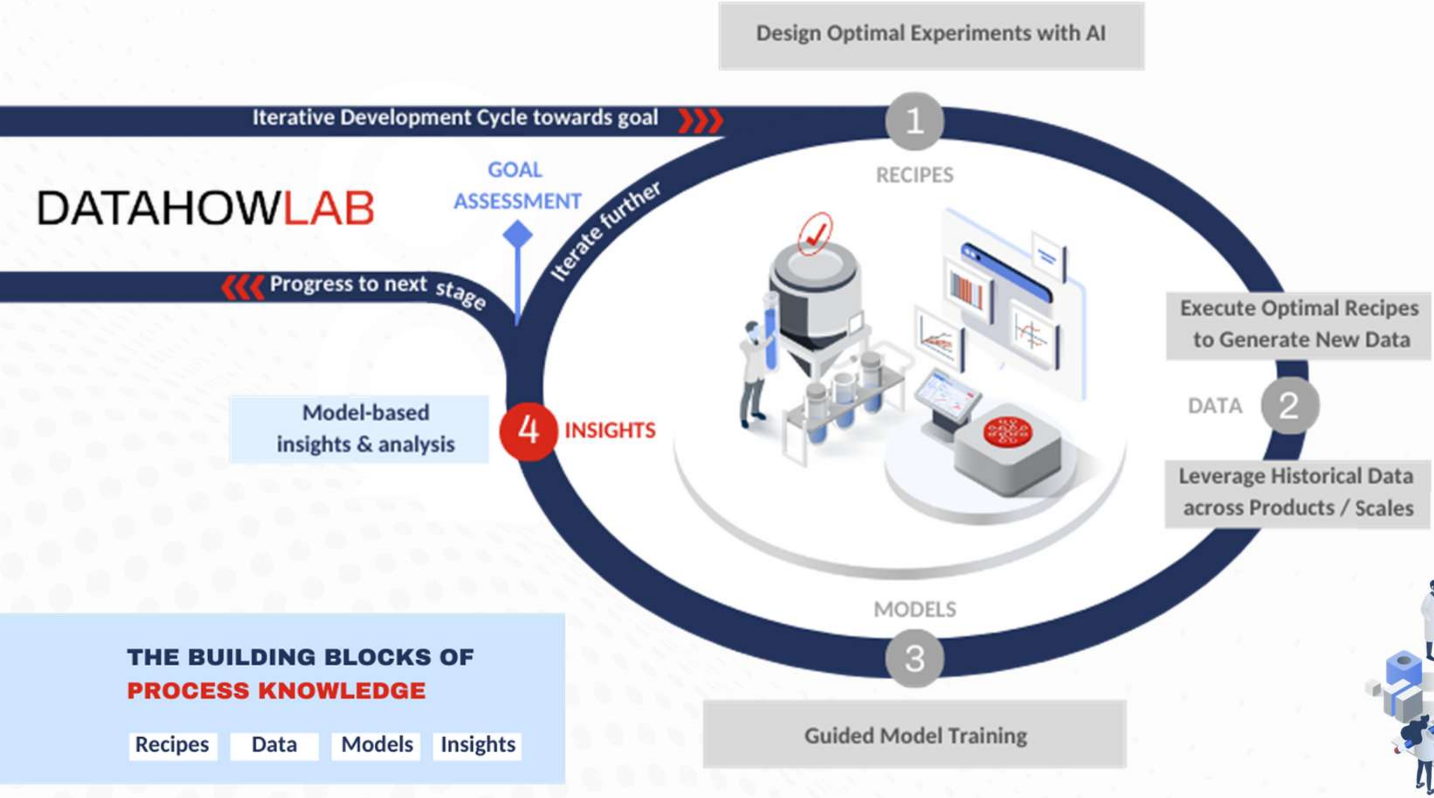
- On average, **Hybrid models** were able to predict CQAs **+35%** better than standard "black box" models
- **Hybrid models** were able to predict CQA's where "black box" models had no clear understanding even after 48 experiments

More insight, with fewer experiments

- Black box models needed **30 experiments** before they could accurately predict CQA values
- Hybrid models only required **10 experiments** to reach the same level of predictive accuracy

Use Advanced Hybrid Models for Key Development Tasks

Democratizing Insight Creation & Use across the Process Lifecycle



4 MODEL BASED DEVELOPMENT TASKS & INSIGHTS

Accumulated Process Knowledge is captured in the Hybrid Models.

They act as a **development aid for process scientists** across key tasks:

- Optimal Experimental Design
- Robustness Analysis
- Scenario Simulations

Output: Process Knowledge for Decision Making

ETH zürich

Mammalian USP

Optimization

Hybrid Models

Selected Case: Optimization of Polishing

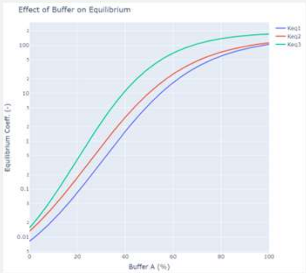
Bayesian Optimization: an optimal trade-off between knowledge and target gains

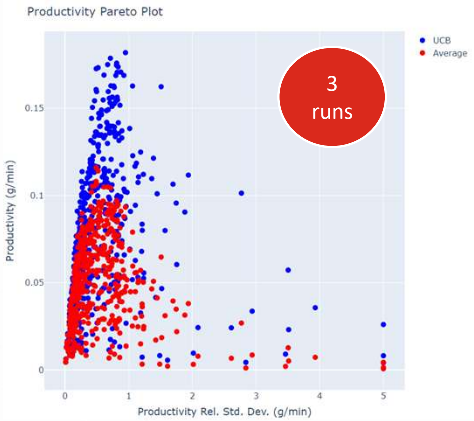
The Project:

Evaluate the ability of **DataHowLab's Hybrid Models** to accurately optimize a chromatographic polishing step and achieve optimal process robustness with minimum number of experiments.

The Challenge:

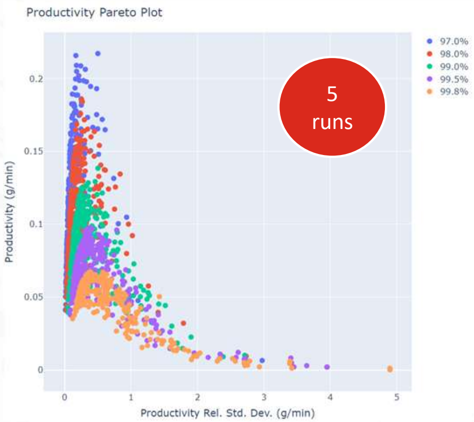
In this insilico example, we emulate the separation of **3 components** with a **gradient chromatography** with a complex definition of selectivity vs buffer composition.





Optimize

Robustify



Fast learning of process and uncertainties

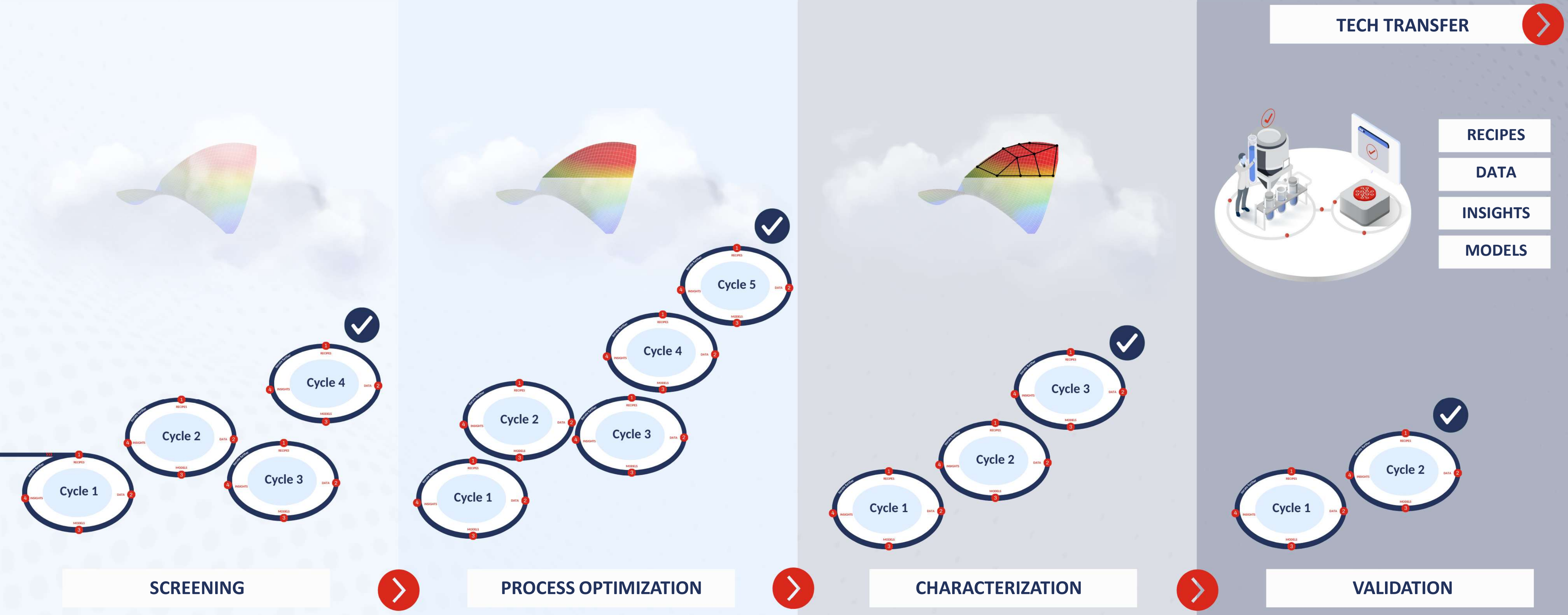
- With only 4 runs, the **hybrid model** was able to learn the complex adsorption behaviour with competition in the presence of buffer gradient
- The **Pareto curves** supports the users to focus new experiments in promising regions to balance optimization and knowledge gain

More insight, better robustness

- With the Pareto plot, we can easily explore the **trade-off** between productivity and specifications (e.g., product purity)
- Through the Monte-Carlo analysis, we can improve **process robustness**, e.g., sensitivity versus peak cutting

A Structured Development Framework across each Stage

Helping Explore and Exploit the Design Space



DataHowLab

AI-Enabled Digital Bioprocessing Platform

A BIOPROCESS SOLUTION FOR BIOPROCESSING

No-code tools, applications, and workflows are adapted for each process format, operation, and lifecycle, to serve the needs of bioprocess scientists.

DATA AS A DEVELOPMENT ASSET

Transfer insights across molecules and scales to leverage historical data, minimize experimental effort, and accelerate development timelines.

DIGITAL DEVELOPMENT FRAMEWORK

Users are guided through development gates to maximally exploit the use of embedded AI technologies towards process goals.

DIGITAL TWINS & PROCESS SIMULATION

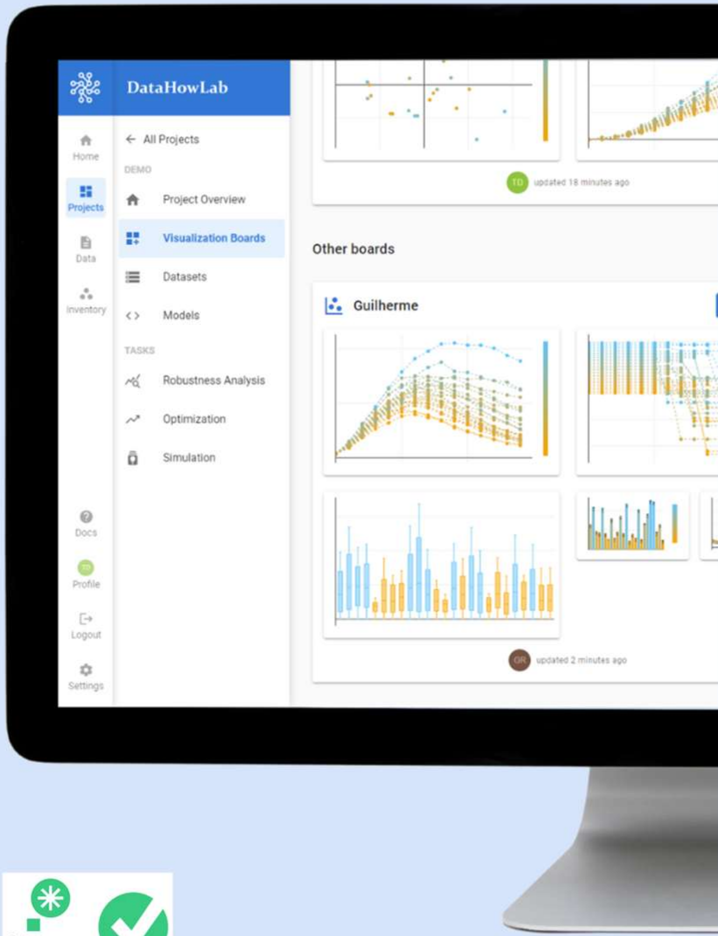
DataHowLab transforms into a digital twin when its powerful hybrid models are combined with process data. True digital bioprocessing.

SINGLE SOURCE OF PROCESS KNOWLEDGE

DataHowLab champions the democratization of process knowledge across the organisation and process lifecycle by storing and deploying insights from shared datasets, projects, and models.

A DIGITAL AUDIT TRAIL FOR YOUR PROCESS

DataHowLab logs every activity taken within the software, providing a detailed audit trail for tech transfer and filing and end-to-end traceability.



POWERED BY AI TECHNOLOGIES ADAPTED TO BIOPROCESSING

tempo audits
ISO/IEC 27001
INFORMATION SECURITY MANAGEMENT SYSTEM

Deploying AI-technologies & solutions

Product roadmap and collaboration opportunities

Available in DHL (Fall 2025)

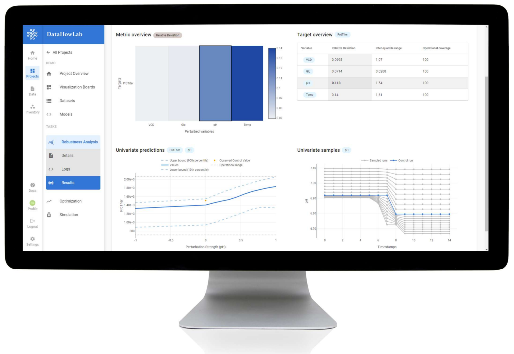
Available in DHL (End 2026)

Process format	Cell Culture	Cell Therapy	Microbial	Gene Therapy	mRNA
Unit operation	Upstream	Chromatography	TFF	Formulation	Spectra
Application goal	Screening	Optimization	Scale-up	Characterization	Manufacturing

Available with DataHowLab

Commercial use of **DataHowLab**.

Customers able to license DataHowLab, as well as access DataHow's support services for optimal software usage.



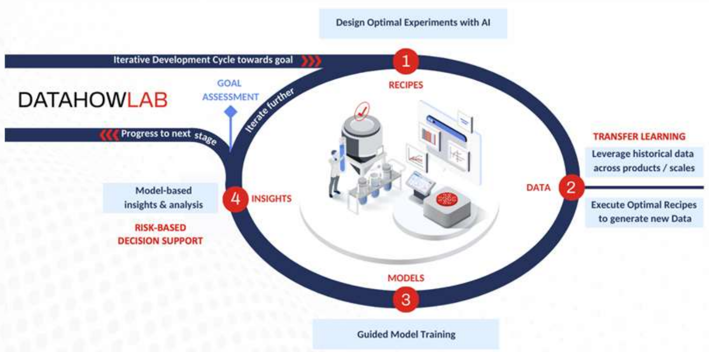
Available as innovation project

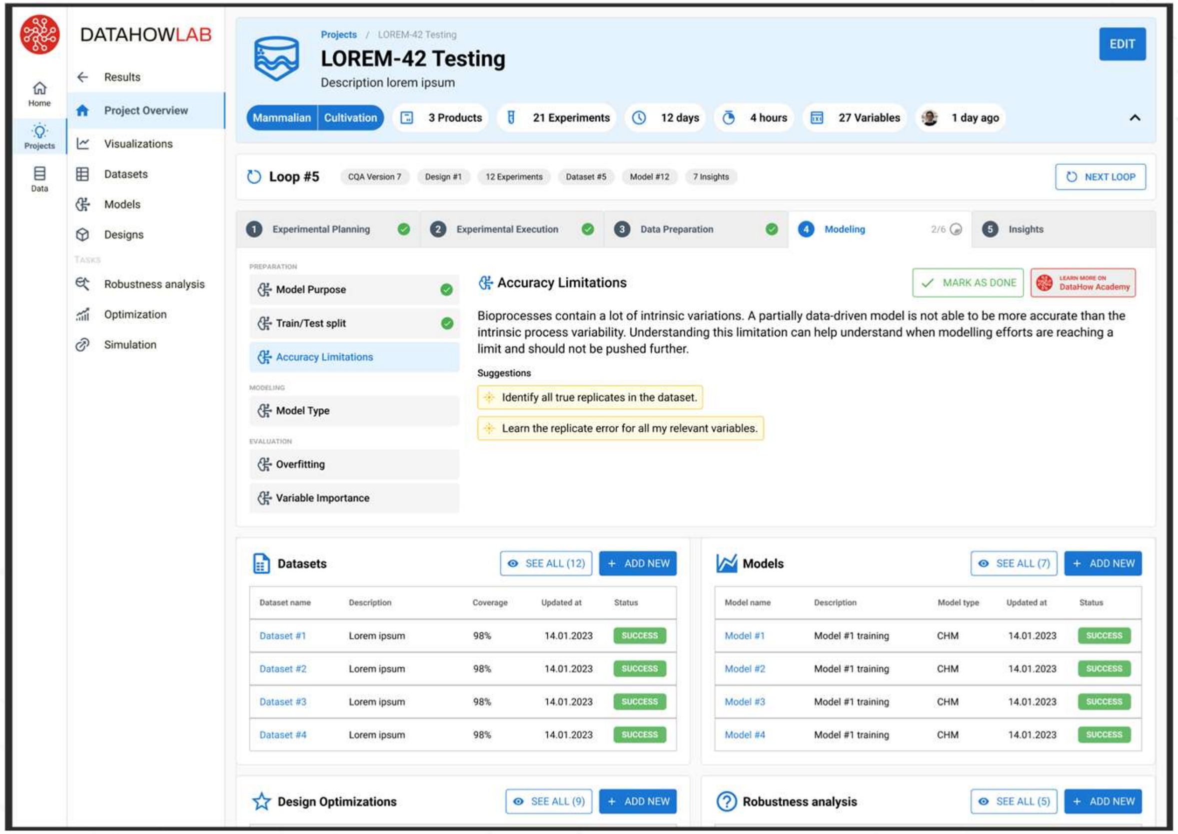
Access to the DataHow team and technology.

Until available within DataHowLab – per the development roadmap – customers are still able to implement the DataHow technology via custom innovation projects across all major and emerging modalities and process operation

Enabling the digital development cycle

Guided for a collaborative and interactive user flow for non-data scientists





Trusted and Deployed by many Key Industry Players

abbvie AMGEN J&J Pfizer Boehringer Ingelheim GSK

BAYER CSL Behring MERCK NOVARTIS Bristol Myers Squibb

novo nordisk Roche sanofi Takeda AstraZeneca ucb

Technology Partners

eppendorf Rockwell Automation Endress+Hauser

securecell cytiva

Academic Partners

ETH zürich POLITECNICO MILANO 1863 TU berlin Imperial College London

Thank you!

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